K100176 1/2

510(k) Summary of Safety and Effectiveness
Ascension® Ankle Fusion Plate System

SUBMITTER NAME: Ascension Orthopedics, Inc.
8700 Cameron Road
Austin, TX 78754-3832

JUN 16 2010

510(k) CONTACT: Debbie Stearns
Phone: (512) 836-5001 x1548

DATE SUMMARY PREPARED: May 27, 2010

TRADE NAME: Ascension® Ankle Fusion Plate System

COMMON NAME: Plate, Fixation, Bone

CLASSIFICATION: 21 CFR 888.3030 – Single/Multiple component metallic bone fixation appliances and accessories

PRODUCT CODE: HRS

PANEL: Orthopedic

PREDICATE DEVICES:
K061940 – Synthes LCP Ankle Arthrodesis Plates
K060473 – Integra Advansys Lateral Tibio-Talar-Calcaneal Plate
K073375 – Integra Tibiaxys

DEVICE DESCRIPTION:
The Ascension® Ankle Fusion Plate System consists of two anterior tibia-talus and a lateral tibia-talus-calcaneus arthrodesis plates. The plates are contoured to the peri articular anatomy and have tapered threaded holes which accept compression or locking threaded screws with a major thread diameter of 4.5 or 6.5mm. All plates and screws will be manufactured from stainless steel or titanium.

INTENDED USE:
The Ascension Ankle Fusion Plate System is intended for the following:

- Arthrodesis of the ankle joint and distal tibia
- Fractures, osteotomies, fusions, and replantations of small bones in the foot and ankle.

SUMMARY OF TECHNOLOGIES:
The technological characteristics of the Ascension Ankle Fusion Plate System are the same, or similar to other legally marketed predicate devices. The Synthes LCP ankle

Arthrodesis (K061940), the Integra Advansys System (K060473), and Integra Tibiaxys have similar designs, same materials and indications.

SUBSTANTIAL EQUIVALENCE:
Ascension Orthopedics believes that this system is substantially equivalent to the legally marketed predicate devices based on similarities in design, materials and indications.

Due to the similarity of materials and design to both pre-enactment and post-enactment devices, it is believed that the Ankle Fusion Plate System does not raise any new safety or effectiveness issues and does not require any nonclinical testing. A comparison of dimensions/sizing addressing worst-case plates between the Ascension Ankle Fusion Plate System and the predicate devices was presented to support substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

JUN 16 2010

Ascension Orthopedics, Inc.
% Ms. Debbie Stearns
8700 Cameron Road
Austin, TX 78754-3832

Re: K100176
Trade/Device Name: Ascension Ankle Fusion Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS, HWC
Dated: June 2, 2010
Received: June 4, 2010

Dear Ms. Stearns:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

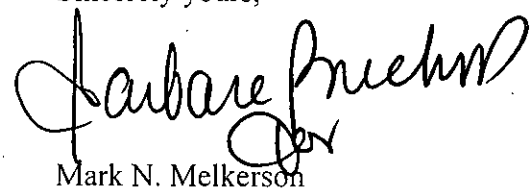
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3 Indications for Use Statement

510(K) Number: K100176

Device Name: Ascension® Ankle Fusion Plate System

Indications for Use:

The Ascension Ankle Fusion Plate System is intended for the following:

- Arthrodesis of the ankle joint and tibia
- Fractures, osteotomies, fusions, and replantations of small bones in the foot and ankle.

Prescription Use ___X___ (Part 21 CFR 801Subpart B) OR Over-The-Counter Use _____ (Part 21 CFR 801Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for mxm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100176